IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., *Plaintiff*, v. AMNEAL PHARMACEUTICALS LLC, *Defendant*.	Civil Action No.: 3:21-cv-08717-RMB-DEA **STIPULATION AND ORDER REGARDING INFRINGEMENT** *Document Filed Electronically*

This stipulation is made by and between Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") and Defendant Amneal Pharmaceuticals LLC ("Amneal") (collectively, the "Parties").

WHEREAS, Amneal filed Abbreviated New Drug Application ("ANDA") No. 215035 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of an oral suspension equivalent to 1 mg/ml amlodipine ("Amneal's ANDA Product");

WHEREAS, Azurity alleges that the filing of Amneal's ANDA infringed claims 1-5, 7-14, and 17-19 of U.S. Patent No. 10,952,998 (the "'998 Patent"); claims 1-5, 7-10, and 14 of U.S. Patent No. 10,695,329 (the "'329 Patent"); and claims 1-5 and 7-17 of U.S. Patent No. 10,894,039 (the "'039 Patent") ("Asserted Claims") under 35 U.S.C. § 271(e)(2)(a), and that the commercial manufacture, use, offer to sell, sale, and/or importation in the United States of Amneal's ANDA Product will infringe the Asserted Claims under 35 U.S. C. §§ 271(a), 271(b), and/or 271(c);

WHEREAS, the parties wish to narrow the issues in this litigation.

NOW THEREFORE, IT IS HEREBY STIPULATED, AGREED, AND ORDERED that:

1. Solely for the purpose of establishing infringement in the above-captioned litigation, including all related appeals, Amneal's ANDA Product meets each and all of the claim limitations of claims 1-5, 7-14, and 17-19 of the '998 Patent.

2. Solely for the purpose of establishing infringement in the above-captioned litigation, including all related appeals, Amneal's ANDA Product meets each and all of the following claim limitations in the '329 Patent:

Claim 1

- An oral liquid formulation
- amlodipine benzoate in an amount corresponding to 1.0 mg/ml amlodipine freebase
- 3mM of a citrate buffer
- 0.2 mg/ml to about 10 mg/ml of sodium benzoate
- 7.5 mg/ml of hydroxypropyl methylcellulose
- 0.15 mg/ml simethicone
- 1.0 mg/ml of polysorbate 80
- water
- wherein the pH of the formulation is between 4 and about 6
- wherein the formulation is stable at 5±5°C. for at least 12 months; and wherein the stable oral liquid formulation has 95% w/w or greater of the initial amlodipine amount and 5% w/w or less total impurities or related substances at the end of the given storage period

Claim 2

- wherein the amlodipine benzoate is formed in situ

Claim 3

- wherein the amlodipine benzoate is formed by a reaction of a pharmaceutically acceptable salt of amlodipine that is more soluble in aqueous media than amlodipine benzoate with a molar excess of sodium benzoate

Claim 4

- wherein the salt of amlodipine that is more soluble in aqueous media than amlodipine benzoate is selected from amlodipine besylate, amlodipine tosylate, amlodipine mesylate, amlodipine succinate, amlodipine salicylate, amlodipine maleate, amlodipine acetate, an amlodipine hydrochloride

Claim 5

- wherein the amlodipine benzoate is formed by the reaction of amlodipine besylate with a molar excess of sodium benzoate

Claim 7

- wherein the formulation further comprises a sweetener

Claim 8

- wherein the sweetener is sucralose

Claim 9

- wherein the formulation is in the form of a suspension

Claim 10

- wherein the pH is between 5 and 6

Claim 14

- wherein the formulation is stable at about 5±5°C. for at least 24 months

3. Solely for the purpose of establishing infringement in the above-captioned litigation, including all related appeals, Amneal's ANDA Product meets each and all of the following claim limitations in the '039 Patent:

Claim 1

- A method of treating hypertension in a subject
- an oral liquid formulation
- amlodipine benzoate in an amount corresponding to 1.0 mg/ml amlodipine freebase
- 3mM of a citrate buffer
- 0.2 mg/ml to about 10 mg/ml of sodium benzoate
- 7.5 mg/ml of hydroxypropyl methylcellulose
- 0.15 mg/ml simethicone
- 1.0 mg/ml of polysorbate 80
- water
- wherein the pH of the formulation is between 4 and about 6
- wherein the formulation is stable at 5±5°C. for at least 12 months; and wherein the stable oral liquid formulation has 95% w/w or greater of the initial amlodipine amount and 5% w/w or less total impurities or related substances at the end of the given storage period

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Claim 7

- wherein the formulation further comprises a sweetener

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- wherein the formulation is in the form of a suspension

Claim 9

- wherein the pH is between 5 and 6

Claim 10

- wherein the formulation is stable at about 5±5°C. for at least 24 months

Claim 11

- wherein the hypertension is primary or secondary hypertension

Claim 12

- wherein the subject has a blood pressure values greater than or equal to $^{140}/_{90}$ mm Hg

Claim 13

- wherein the wherein the formulation is administered to the subject in a fasted state or a fed state

Claim 14

- wherein the subject is an elderly

Claim 15

- wherein the subject is an adult

Claim 16

- wherein the subject is a child

Claim 17

- wherein the formulation is further administered in combination with an agent selected from the group consisting of diuretics, beta blockers, alpha blockers, mixed alpha and beta

blockers, calcium channel blockers, angiotensin II receptor antagonists, ACE inhibitors, aldosterone antagonists, and alpha-2 agonists

February 3, 2023

Respectfully submitted,

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Attorneys for Plaintiff Amneal Pharmaceuticals LLC

SO ORDERED this 21st day of February, 2023.

HONORABLE RENÉE MARIE BUMB
CHIEF UNITED STATES DISTRICT COURT JUDGE